Remarks

I. Support for Amendments and Status of the Claims

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendments, claims 1, 2, 11, 13-42 and 44-106 are pending in the application, with claims 1, 13, 44, 58, 62, 65 and 100 being the independent claims. Claims 3-10, 12 and 43 have been cancelled without prejudice to or disclaimer of the subject matter contained therein. Amendment is sought to claims 1, 11, 13-20, 22-27, 29-31, 33, 36-42, 44-48 and 50 to ensure that the claims more closely conform to USPTO practice. Claims 1 and 13 have also been amended to recite a virus-like particle comprising a protein comprising amino acids 2-131 of SEQ ID NO:1. This amendment is fully supported by the specification as filed, including paragraphs [0084] to [0086] and, thus, does not introduce new matter.

New claims 52-106 are sought to be entered. The new claims are fully supported by the specification and original claims and do not introduce new matter. New claims 58, 60, 61, 65 and 100 recite, *inter alia*, a virus-like particle comprising a protein comprising amino acids 2-131 of SEQ ID NOs:1 or 3. As with claims 1 and 13, these elements are supported by the specification as filed, including paragraphs [0045], [0084] to [0086] and, thus, do not introduce new matter.

Amendment to the specification is sought to correct a typographical error in paragraphs [0030], [0263] and [0264]; these amendments do not introduce new matter. Amendment to paragraph [0030] is also sought to clarify the brief description of Figures 1A-E, as requested by the Examiner in the present Office Action. This description was incorporated into the present application by reference from the parent, U.S. provisional Application No. 60/396,126. Accordingly, this amendment does not introduce new

matter, but merely makes explicit that which was already at least implicit in the present specification.

II. Summary of the Office Action

In the Office Action dated June 24, 2005, (hereinafter "Office Action") at pages 2 to 3, the Examiner has rejected claims 1-12, 16-28, 30, 41, 42 and 46-51 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. At pages 3 and 4 the Examiner has rejected claims 1-5, 7-46 and 48-51 under 35 U.S.C. § 112, first paragraph, as allegedly lacking in written description. At pages 4 and 5 the Examiner has rejected claims 6 and 47 under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the enablement requirement. At page 6 the Examiner has rejected claims 1-5, 7-10, 12-27, 29, 30 and 40-46 under 35 U.S.C. § 102(b) as allegedly anticipated by Schiller *et al.* (WO 00/23955).

In addition to the above rejections the Examiner, at page 5, has also objected under 37 C.F.R. § 1.75 to claims 3, 7 and 8 as allegedly being duplicates of claim 1; to claims 50 and 51 as being of improper form; and to the specification for an informality in the "Brief Description of the Drawings." At pages 6 to 9 the Examiner has issued the following provisional double patenting rejections: of claims 1-5, 7-46 and 48-51 over the claims of copending Application Nos. 09/848,616, 10/050,902, and 10/243,739; of claim 30 over the claims of copending Application Nos. 10/050,898, 10/264,267, 10/289,456, and 10/289,454; of claim 32-35 over the claims of Application No 10/622,064; and of claims 25, 26 and 28 over the claims of copending Application No. 10/733,852. At page 10, the Examiner has remarked on Applicant's Information Disclosure Statement filed

November 14, 2003. Finally, at pages 9 and 10, the Examiner has identified subject matter which was considered allowable.

Applicants respectfully offer the following remarks concerning each element of the Office Action, and request reconsideration of the present application in view of these remarks.

III. Allowable Subject Matter

At pages 9 and 10 of the Office Action, the Examiner has indicated the presence of allowable subject matter. Solely to advance prosecution, Applicants present herewith amended claims 1, 11, 13-20, 22-27, 29-31, 33, 36-42, 44-48 and 50 and new claims 52-57 which correspond to the subject matter which the Examiner considers allowable. An indication of allowability of these claims as currently presented is therefore respectfully requested.

IV. Objections to the Specification

At pages 5 and 6 of the Office Action the Examiner has objected to the specification for an alleged informality in paragraph [0030] of the "Brief Description of the Drawings," which makes reference to AP205 virus and virus-like particles in Figures 1A-B, while the drawings include Figures 1A-E. As required by the Examiner, the brief description of the drawings at paragraph [0030] has been amended to provide a brief description of Figures 1A-E, and paragraphs [0030], [0263] and [0264] have been amended to indicate that Figures 1D and 1E depict AP205 virus and virus-like particles, respectively. Therefore the objection has been fully accommodated. Entry of these

amendments and reconsideration and withdrawal of the objection to the specification are respectfully requested.

V. Objections to the Claims

At page 5 of the Office Action the Examiner has objected to claims 3, 7 and 8 under 37 C.F.R. § 1.75 as allegedly being duplicates of claim 1. By the foregoing amendments, claim 1 has been amended and claims 3, 7 and 8 have been cancelled without prejudice to or disclaimer of the subject matter therein, rendering moot the Examiner's present objection to allegedly duplicate claims.

At page 5 of the Office Action the Examiner has also objected to claims 50 and 51 as allegedly being in improper form for a multiple dependent claim. Applicants have accommodated the Examiner's objections by the foregoing amendment to claim 50.

All grounds of objection to the claims have been rendered moot or accommodated by amendment. Reconsideration and withdrawal of the objections to the claims are respectfully requested.

VI. Obviousness-Type Double Patenting

At pages 6-9 of the Office Action the Examiner has issued the following provisional obviousness-type double patenting rejections; of present claims 1-5, 7-46 and 48-51 over the claims of copending Application Nos. 09/848,616, 10/050,902, and 10/243,739; of present claim 30 over the claims of copending Application Nos. 10/050,898, 10/264,267, 10/289,456, and 10/289,454; of present claim 32-35 over the claims of Application No. 10/622,064; and of present claims 25, 26 and 28 over the

claims of copending Application No. 10/733,852. Applicants respectfully traverse these rejections.

Of those claims that the Examiner has provisionally rejected over the claims of copending applications listed above, claims 3-5, 7-10, 12 and 43 have been cancelled without prejudice or disclaimer, rendering moot the provisional rejection of these claims. Of the remaining provisionally rejected claims, claims 1, 11, 13-20, 22-27, 29-31, 33, 36-42, 44-48 and 50 have been amended.

The present claims are patentably distinct from at least several of the claims of the copending related applications that were cited by the Examiner in making the present provisional obviousness-type double patenting rejection. For example, Applicants note that the amino acid sequence of the coat protein of AP205 is not homologous to any other protein in the database, a point also made by the Examiner at page 4 of the Office Action. The coat protein of AP205 is thus readily distinguishable from other proteins, including those that may be used to form core particles. It follows that, since the present claims are drawn to core particles comprising polypeptides derived from AP205 coat proteins, the subject matter of these claims is distinguishable from claims that are specifically drawn to core particles comprising polypeptides that are not derived from AP205.

For example, claim 86 of copending (now allowed) U.S. Application No. 09/848,616 ("the '616 application"), and its dependent claims, are drawn to core particles comprising a polypeptide derived from Hepatitis B virus. Claim 86 of the '616 application recites a core particle comprising:

> a virus-like particle that is a dimer or a multimer of a polypeptide comprising, as a core particle, a polypeptide having the amino acid sequence of SEQ ID NO:158, modified such that the cysteine residues at positions 48 and 110 of SEQ ID NO:158 (corresponding to positions 48

and 107 of SEQ ID NO:134) are either deleted or substituted with another amino acid, or a sequence having at least 90% sequence identity to said polypeptide sequence and in which the cysteine residues at positions 48 and 110 of SEQ ID NO:158 are either deleted or substituted with another amino acid.

SEQ ID NO: 158, recited in this claim, is derived from Hepatitis B virus. Accordingly, the claims of the present application, which are drawn to particles comprising the AP205 coat protein, are patentably distinct from those of the '616 application which are drawn to particles comprising a polypeptide derived from Hepatitis B virus.

The Examiner has also provisionally rejected the present claims over claims 220-361 of copending Application No. 10/050,902 ("the '902 application"). However, following Applicants' August 29, 2005, Amendment and Reply in the '902 application, claims 263, 264, 273, 274, 281, 282, 286-291, 298, 299, 307, 308, 317, 318, 321-328, 333 and 334 were cancelled from that application. Of the remaining pending claims in the '902 application, at least claims 221, 222, 223, 224, 226, 227 and 228 recite core particles derived from species of viruses such as Qβ, fr or GA. These core particles are distinct from those derived from AP205, as elaborated above. Accordingly, the claims of the present application are patentably distinct from at least claims 221, 222, 223, 224, 226, 227 and 228 of the '902 application.

Applicants also traverse the remaining provisional obviousness-type double patenting rejections on analogous grounds. Given that the present claims have been amended, and in the interests of efficient prosecution, if the Examiner is inclined to maintain the present provisional rejections notwithstanding the above remarks Applicants request that the Examiner hold the present provisional obviousness-type double patenting rejections in abeyance until the identification of otherwise allowable

claims in the present application. At such a time, Applicants will consider filing any necessary terminal disclaimers.

VII. Rejection Under 35 U.S.C. § 102(b)

At page 6 of the Office Action the Examiner has rejected claims 1-5, 7-10, 12-27, 29, 30 and 40-46 under 35 U.S.C. § 102(b) as allegedly being anticipated by Schiller *et al.*, WO 00/23955 ("Schiller"). Applicants respectfully traverse this rejection.

As an initial matter Applicants note that, of the rejected claims, claims 3-5, 7-10 and 43 have been cancelled without prejudice or disclaimer, rendering moot the rejection of those claims. The following remarks apply to that portion of the rejection that may be applied to the remaining claims.

Upon entry of the foregoing amendments, claims 1, 13, 44, 60, 61, 65 and 98 generally recite that the core particle comprises a protein with amino acids 2-131 of SEQ ID NO:1; amino acids 2-131 of SEQ ID NO:3; and/or a mutein of SEQ ID NO:1, wherein said mutein consists of an addition, deletion or substitution of one to three amino acids from amino acids 1-131 of SEQ ID NO:1. Accordingly, the present claims are not anticipated by the compositions of Schiller, which do not comprise the proteins recited in the present claims and which are limited to VLPs of bovine papillomavirus L1, a DNA animal virus. Hence, Schiller does not disclose every element of the present claims. Applicants therefore respectfully request reconsideration and withdrawal of the Examiner's rejections under 35 U.S.C. § 102(b).

VIII. Rejections Under 35 U.S.C. § 112, Second Paragraph

In the Office Action at pages 2 to 3 the Examiner has rejected claims 1-12, 16-28, 30, 41, 42 and 46-51 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Applicants respectfully traverse. As an initial matter, Applicants have cancelled claims 3-10 and 12 without prejudice or disclaimer, rendering moot this rejection as it may have been applied to those claims. Applicants have also sought to amend claims 1, 11, 13-20, 22-27, 29-31, 33, 36-42, 44-48 and 50, and have added new claims 52-106. Applicants respectfully traverse this rejection as it may be applied to the present claims.

The Examiner has initially rejected claims 1, 25-28, 30 and 50 as allegedly indefinite for recitation of "a mutein." Present claims 1, 25-28, 30 and 50 have been amended to remove this recitation, obviating this portion of the rejection. New claims 58, 61, 65 and 100 recite that said mutein consists of an addition, deletion or substitution of one to three amino acids from amino acids 1-131 of SEQ ID NO:1. Accordingly, those of ordinary skill in the art would recognize that the present claims do not encompass an indefinite and infinite variety of polypeptides.

The Examiner has next rejected claims 1 and 47 as allegedly indefinite for recitation of "an amino acid sequence as set forth in SEQ ID NO:1." Applicants have amended the claims to remove the language which forms the basis for this portion of the Examiner's rejection. Claim 1 recites "at least one protein comprising amino acids 2-131 of SEQ ID NO:1" and claim 47 recites "the nucleotide sequence as set forth in SEQ ID NO:125." Accordingly, this aspect of the rejection has been obviated.

The Examiner's rejection of claims 3-5 and 8-10 has been rendered moot by cancellation of those claims, without prejudice to or disclaimer thereof.

The Examiner's rejection of pending claims 16-20 and 22 for recitation of a broad range together with a narrow range has been overcome by amendment to the claims to remove the language which forms the basis of this aspect of the rejection.

Finally, the Examiner has rejected claim 41 for recitation in the preamble of the term "vaccine" which is allegedly different in scope from the term "immunologically effective." Applicants have obviated the Examiner's rejection by removing these terms from the claims, without prejudice to or disclaimer thereof.

All grounds of rejection under 35 U.S.C. § 112, second paragraph, for indefiniteness have been rendered moot or obviated. Applicants therefore respectfully request that the Examiner reconsider and withdraw the present rejections.

IX. Rejections Under 35 U.S.C. § 112, First Paragraph, Enablement

In the Office Action at pages 4-5, the Examiner has rejected claims 6 and 47 under 35 U.S.C. § 112, first paragraph, as allegedly being nonenabled. Claim 6 has been cancelled without prejudice or disclaimer, rendering moot the rejection of claim 6. Applicants respectfully traverse this rejection as it may be applied to claim 47, as currently presented, in view of the following remarks. For the same reasons, Applicants also contend that new claims 58-106 should not be subject to rejection under 35 U.S.C. § 112, first paragraph for lack of enablement.

The Examiner has asserted that "alteration of coat protein structure has unpredictable effects upon the ability to form a particle, and there is no evidence on this record that SEQ ID NO:3 is able to form a particle. If it cannot, then the specification does not teach any method of use for the protein or its coding sequence." Office Action at page 4, line 20 to page 5, line 1. Applicants respectfully disagree.

Applicants remind the Examiner that in order to enable a claimed invention, a specification need not even disclose working examples. "Nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples." *In re Wright*, 27 U.S.P.Q.2d 1510, 1561 (Fed. Cir. 1999); *see also In re Borkowski*, 422 F.2d 904, 908 (C.C.P.A. 1970) ("a specification need not contain a working example if the invention is otherwise disclosed in such a manner that one skilled in the art will be able to practice it without an undue amount of experimentation."); *In re Long*, 151 U.S.P.Q. 640, 642 (C.C.P.A. 1966) ("absence of a working example does not in and of itself compel the conclusion that a specification does not satisfy the requirements of section 112."). Rather, the enablement requirement of 35 U.S.C. § 112, first paragraph, is satisfied if the claimed invention is enabled so that any person skilled in the art can make and use the invention without undue experimentation. *See In re Wands*, 858 F.2d 731, 737, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988).

Applicants note that the specification at paragraph [0010] states that "the invention provides assembly competent mutant forms of AP205 VLPs, including AP205 coat protein with the substitution of proline at amino acid 5 to threonine (SEQ ID NO: 3)." In order to establish a *prima facie* case of non-enablement the Examiner has the initial burden to set forth a reasonable basis to question the enablement provided for the claimed invention. *See In re Wright*, 999 F.2d 1557, 1562, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993) holding that:

> When rejecting a claim under the enablement requirement of section 112, the PTO bears the initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by the claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the

scope of enablement. If the PTO meets this burden, the burden then shifts to the Applicant.

Applicants have clearly and explicitly taught that one of ordinary skill in the art can make and use AP205 VLPs comprising SEQ ID NO:3, as recited in present claim 47. The PTO bears the burden to provide sufficient reasons to doubt the assertions set forth in the specification. Applicants assert that this burden has not been met.

Even if one of ordinary skill in the art had not been so taught by the present specification, it would not require undue experimentation to determine if a given protein comprising the amino acids of SEQ ID NO:3 (as recited in claim 47), or any mutein of SEQ ID NOs:1 or 3 (as recited in claims 58-106), assembles into virus-like particles. For example, the present specification at paragraph [0085] states that those of ordinary skill in the art can readily determine if a vector expresses protein and then if such a protein is capable of assembly into VLPs:

> suitable combinations of vectors and strains can be identified by testing expression of the coat protein by SDS-PAGE and capsid formation and assembly by optionally first purifying the capsids by gel filtration and subsequently testing them in an immunodiffusion assay (Ouchterlony test) or Electron Microscopy (Kozlovska, T. M.. *et al.*, *Gene 137*:133-37 (1993)).

Paragraph [0087] also provides that "[t]he outcome of insertions, deletions and fusions to the coat protein sequence and whether it is compatible with assembly into a VLP can be determined by electron microscopy." Even more, Examples 1 and 2 *expressly* demonstrate how one of ordinary skill in the art can readily clone a sequence expressing AP205 viral coat proteins, express and purify the proteins, determine that the expressed proteins assemble into VLPs, and show that such VLPs are indistinguishable from wild-type AP205 bacteriophage particles. As one of ordinary skill in the art would readily

appreciate, the methods described in these portions of the specification are well within the level of ordinary skill in the art and thus represent nothing more than "routine experimentation." Accordingly, undue experimentation is not required to demonstrate that a particular phage coat protein, or a mutein or fragment thereof, is able to assemble into a VLP. Applicants have demonstrated that the specification fully enables the claimed invention in that undue experimentation is not necessary to make and use the presently claimed invention.

Furthermore, Applicants provide herewith the attached Declaration of Martin Bachman Under 37 C.F.R. § 1.132. At paragraphs 5 and 6 of his declaration Dr. Bachmann attests that:

> I, or others working under my supervision, have prepared virus-like particles (VLPs) from proteins having the amino acid sequence set forth in SEQ ID NO: 3. To prepare these VLPs, *E. coli* was transformed with plasmid pAP281-32 of Example 1, and cultured as described in Example 2. *E.coli* lysate was prepared essentially as described in Example 2, with the slight modification that lysozyme was used in the lysis buffer, and the cells subjected to three freeze-thaw cycles instead of sonication, an alternative well-known to a person of ordinary skill in the art. The lysate was then examined by electron microscopy using standard methods.
>
> The attached **Figure A** shows an electron micrograph of virus-like particles formed from proteins having the amino acid of SEQ ID NO:3, using the methods referenced in paragraph 5 herein. The abundant capsids of shape indistinguishable from AP205 bacteriophage obtained in the lysate of *E. coli* expressing AP205 coat protein of SEQ ID No: 3 demonstrates that the mutation in the capsid protein does not interfere with assembly of the particles in *E.coli*. The abundant and regularly shaped capsids obtained in the lysate and shown in Figure A thus demonstrate that AP205 coat protein of SEQ ID No:3 assembles in *E.coli* to VLPs.

At paragraph 7 of his declaration Dr. Bachmann concludes that:

> Therefore, a protein having the amino acid of SEQ ID NO:3 is able to form virus-like particles, confirming the disclosure of the same in the present application, *e.g.* at paragraph [0010].

Accordingly, a person of ordinary skill in the art, following the teachings of the present specification, would have been able to produce virus-like particles from a protein having an amino acid sequence of SEQ ID NO:3.

For at least these reasons the full scope of claim 47 is enabled by the specification. Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement. For the same reasons, Applicants contend that new claims 58-106 should also not be subject to rejection under 35 U.S.C. § 112, first paragraph for lack of enablement.

X. Rejections Under 35 U.S.C. § 112, First Paragraph, Written Description

At pages 3 and 4 of the Office Action the Examiner has rejected claims 1-5, 7-46 and 48-51 under 35 U.S.C. § 112, first paragraph, for alleged lack of written description. Applicants respectfully traverse. As an initial matter, Applicants have cancelled claims 3-5, 7-10, 12 and 43 without prejudice or disclaimer, rendering moot the Examiner's rejection of those claims. In addition, pending claims 1, 11, 13-20, 22-27, 29-31, 33, 36-42, 44-48 and 50 have been amended to be drawn to subject matter which the Examiner stated in the present Office Action was allowable, thus obviating the present grounds of rejection. Reconsideration and withdrawal of the rejection is respectfully requested.

Applicants also wish to offer the following remarks concerning why this rejection should not be applied to new claims 58-106. As recently reiterated by the Federal Circuit, the crux of the question concerning whether a claimed invention is adequately described is whether one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention in the specification as filed. *See Moba, B.V. v.*

Diamond Automation, Inc., 325 F.3d 1306, 1320 (Fed. Cir. 2003) (citing *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991)); *see also* M.P.E.P. § 2163.02. The Federal Circuit in *Eli Lilly* set forth several tests for whether a claimed genus is adequately described, including the "representative number of species" test and the "common structural features" test. *Regents of the Univ. of Calif. v. Eli Lilly & Co.*, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). However, the court also stated that "[w]e will not speculate in what *other ways* a broad genus of genetic material may be properly described." *Id.* (emphasis added). It is also important to recognize that the specification does not have to describe that which is already in possession of those of ordinary skill in the art. *See, e.g.*, *Capon v. Eshhar,* 481 F.3d 1349, 76 U.S.P.Q.2d 1078 (Fed. Cir. 2005).

Thus, there is no fixed set of tests for whether a claimed genus is adequately described. Instead, the determination of compliance with the written description requirement is a fact-based one, and in cases subsequent to *Eli Lilly*, the Federal Circuit has limited the holding in *Eli Lilly* to its particular set of facts. *See, e.g.*, *Moba* at 1320; *see also Amgen Inc. v. Hoechst Marion Roussel Inc.*, 314 F.3d 1313, 1332 (Fed. Cir. 2003); *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 63 U.S.P.Q.2d 1609, 1613 (Fed. Cir. 2002).

In the present case, the Examiner has asserted at pages 3-4 of the Office Action that:

> The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims involve a genus of virus-like particles or virus particles. The specification shows a reduction to practice of virus-like particles with the sequence SEQ ID NO:1. The specification also shows reduction to practice of a protein with SEQ ID NO:3, where proline at position 5 is changed to threonine, and discusses

> additional variations in the sequence such as removal of cysteine(s) and alteration of lysine(s). However, there is no showing that any of the variants, even SEQ ID NO:3, actually assembles into particles. . . . The specification contains no teachings regarding the minimal structural requirements for AP205 muteins to assemble into particles and the absence of homology to known coat proteins precludes any prediction of essential or nonessential residues or regions. Considering the absence of teachings, the unpredictable effect of amino acid changes on assembly into particles, the absence of knowledge in the prior art, and the single species reduced to practice, it is concluded that the specification reasonably conveys possession only of VLPs or virus particles comprising SEQ ID NO:1. This is a "written description" rejection, not an enablement rejection.

The basis of the rejection thus appears to be whether the specification conveyed, to one of ordinary skill in the art, a sufficient number of *working* embodiments.

Applicants wish to remind the Examiner that "[a]dequate description under the first paragraph of 35 U.S.C. 112 does not require *literal* support for the claimed invention . . . . the observation of a lack of literal support does not, in and of itself, establish a *prima facie* case for lack of adequate descriptive support under the first paragraph of 35 U.S.C. 112." *Ex parte Parks*, 30 U.S.P.Q.2d 1234, 1236 (Bd. Pat. App. Int. 1994). Instead, the written description requirement of 35 U.S.C. § 112, first paragraph, is met "if the originally-filed disclosure would have conveyed to one having ordinary skill in the art that an [applicant] had possession of the concept of what is claimed," *id.*, *i.e.*, "[i]f a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification . . . ." *In re Alton*, 37 U.S.P.Q.2d 1578, 1584 (Fed. Cir. 1996). An Applicant is not required to disclose or provide a working example of every species of a given genus in order to meet the written description requirement of 35 U.S.C. § 112 (*see Parks* and *Alton*), and subject matter that "might fairly be deduced from the original application" is considered to be

described in the application as filed. *Acme Highway Products Corp. v. D.S. Brown Co.*, 431 F.2d 1074, 1080 (6th Cir. 1970) (citations omitted), *cert. denied*, 401 U.S. 956 (1971), *followed by Westphal v. Fawzi*, 666 F.2d 575, 577 (C.C.P.A. 1981). Accordingly, the test is not how many working embodiments were disclosed, but whether the specification conveys that which *is* claimed.

Claims 58-106 recite a defined genus of proteins that differ from SEQ ID NO:1 by no more than 3 amino acids *and* form virus-like particles. This narrower genus is within the scope of a much larger genus described by the specification. The specification clearly describes both SEQ ID NOs:1 and 3, the nucleotides that encode them, and muteins thereof, as also noted by the Examiner. As discussed above, the specification also demonstrates that such proteins are able to form VLPs. The specification also provides for assembly competent mutant forms of AP205, and specifically discusses SEQ ID NO:3 in this context at paragraph [0010], which states that:

> The present invention provides recombinantly expressed virus-like particles (VLPs), spontaneously assembled from at least one coat protein of bacteriophage AP205 recombinantly expressed in *E. coli*. In a related aspect, the invention provides assembly-competent mutant forms of AP205 VLPs, including AP205 coat protein with the substitution of proline at amino acid 5 to threonine (SEQ ID NO: 3).

Applicants have therefore provided at least two "working" embodiments (SEQ ID NOs:1 and 3) of the invention as claimed in new claims 58-106. In *Amgen*, the Federal Circuit concluded that the claims at issue were adequately described, even though the specification described *only two species* within the genus. *Amgen* 314 F.3d 1313.

Even if the specification had not disclosed these working embodiments, the specification would still provide sufficient written description to support the present claims. The Federal Circuit has recently reaffirmed the concept that knowledge available

to those of ordinary skill in the art does not need to be explicitly recited in the specification. *See Capon v. Eshhar,* 481 F.3d 1349, 76 U.S.P.Q. 2d 1078 (Fed. Cir. 2005). Hence, in view of the knowledge readily available in the art, the specification has provided sufficient information to allow those of ordinary skill to identify assembly competent muteins of SEQ ID NOs:1 and 3.

In summary, Applicants assert that the specification reasonably conveys the presently claimed invention to those of ordinary skill in the art, and demonstrates that Applicants had possession of the claimed invention as of the filing date of the present application. Applicants therefore respectfully contend that new claims 58-106 should not be subject to rejection under 35 U.S.C. § 112, first paragraph, for alleged lack of written description.

Conclusion

All of the stated grounds of rejection have been properly traversed, accommodated or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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